IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT:	Xiong et al.
SERIAL NO.:	10/723,435
FILED:	November 26,2003
FOR:	TRANSDERMAL ADMINISTRATION OF HUPERZINE
ART UNIT:	1615
EXAMINER:	Ghali, I.
DOCKET NO.:	T8341.NP.CON

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DECLARATION OF DANYI QUAN
UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I, Danyi Quan, declare as follows:

1. I am the Chief Science Officer for the assignee of the above patent application, have 20 years experience in the pharmaceutical academy and industries; served as an Assistant Professor and laboratory director at the Department of TCM (Traditional Chinese Medicine), School of Pharmacy, China Pharmaceutical University; and received a Ph.D. degree in Pharmaceuticals under

the supervision of Dr. Tsunaji Nagai, a world-famous professor in advanced drug delivery fields.

2. It is my understanding that various claims in the above-recited patent application have been rejected in view of United States Patent 6,352,715, (hereinafter "the '715 patent") patented on March 5, 2002, and Chinese Patent 1,111,987, (hereinafter "the '987 patent ") published November 22, 1995.

3. I have reviewed the '715 patent and the '987 patent and am familiar with the methods of making transdermal patches as described therein.

4. I have prepared Huperzine patches using the methods and teachings described in the '715 patent and the '987 patent and compared them to the Huperzine patches of the present application.

5. Specifically, I have prepared Huperzine patches with roughly equivalent amounts of adhesive, Huperzine, and coating weights using the following general protocols in accordance with the teachings described in the '715 patent, the '987 patent, and the present application: the adhesive was weighted into glass bottles; and then the drug was added; approximately 8 ml of a given casting solution was then dispensed on a release liner, and cast with a gap casting knife; the cast was dried in a convection oven at 100~110°C for 5 minutes to yield a dry film weighing ranged from 5 to 7 mg /cm^2; the backing film was then laminated onto this adhesive film using a rubber roller; and finally, the matrix laminate was used to conduct in vitro skin flux studies.

6. For the '715 patch, I further used the following method in accordance with the teachings described therein: 1N NaOH aqueous solution was added to adjust the pH of the casting solution to pH 9; the glass bottle was then tightly capped, sealed with parafilm, and rotated overnight (notably, since the 1N NaOH aqueous solution can't be well mixed with

solvent-based adhesive, a phase separation occurred in the casting solution, and made the casting solution turn to cloudy color).

7. I have graphed the resulting data obtained from the '715 patch as compared to the present patch, the disclosed '715 data of Figure 11, and the resulting data obtained from the '987 patch as compared to the present patch, in Exhibits A, B, and C, which are attached herewith.

8. The patches of the present invention provide a sustained delivery of Huperzine at a minimum specified dose for at least 3 days, while the patches of the '715 patent and the '987 patent do not sustain delivery at the minimum dose.

9. One skilled in the art could not create a transdermal patch which delivers Huperzine at the required dose in a safe and efficacious manner for at least 3 days of sustained delivery by following the contents of the '715 patent and/or the '987 patent.

10. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful, false statement may jeopardize the validity of the application or any patent issuing thereon.

DATED this 30th day of August, 2007.

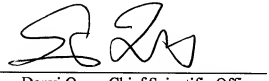

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EXHIBIT A

Comparison of Daily Delivery of Huperzine A

- Xel Matrix Patch vs. Matrix Patch with pH Adjusted to 9

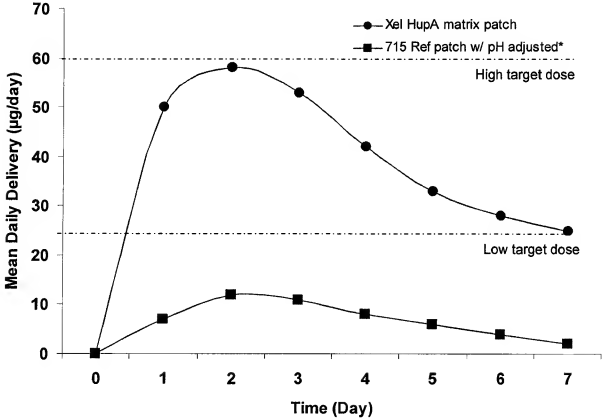

EXHIBIT B

US Patent 6,352,715 - Figure. 11

Daily Delivery of Huperzine A from A Transdermal System

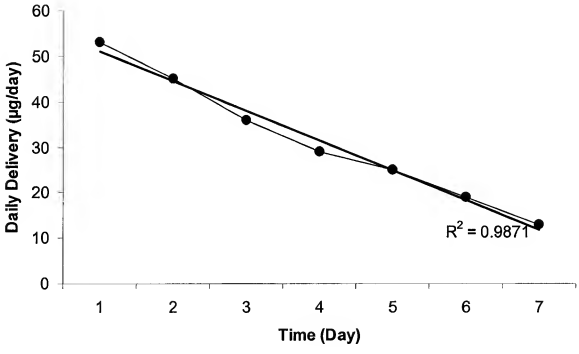

EXHIBIT C

Comparison of Daily Delivery of Huperzine A through Xel Prototype Matrix System vs. Matrix System Containing Azone